

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1. (withdrawn): A composition for the co-delivery to a cell of a nucleic acid and an assistor protein comprising vesicles formed of amphiphilic components, wherein the nucleic acid operatively encodes an antigenic protein or portion thereof which shares at least one epitope with the assistor protein, the composition comprising said nucleic acid and said assistor protein associated with the same vesicles as one another.
2. (withdrawn): A composition according to claim 1 wherein the vesicles are liposomes formed from liposome forming materials and said nucleic acid and said assistor protein are associated with the liposomes.
3. (withdrawn): A composition according to claim 2 in which the nucleic acid is entrapped in the intravesicular space of the liposome.
4. (withdrawn): A composition according to claim 2 in which the assistor protein is accessible at the outer surface of the liposomes.
5. (withdrawn): A composition according to claim 1 in which the amphiphilic components include at least one cationically charged component in an amount such that the vesicles have an overall positive charge.
6. (withdrawn): A composition according to claim 5 in which the cationic component is selected from 1,2-bis(oleoyloxy)-3-(trimethylammonio)propane (DOTAP), 1,2-

bis(hexadecyloxy)-3-trimethylaminopropane (BisHOP), β [1-(2,3-dioleyloxy)propyl]-N,N,N-triethylammoniumchloride (DOTMA) and 3β -(N,N-dimethylaminoethane)carbamylcholesterol (DC-CHOL).

7. (withdrawn): A composition according to claim 1, in which the nucleic acid comprises more than one molecule each of which encodes a different antigenic protein, and in which the assistor protein includes corresponding proteins sharing epitopes with each such antigenic protein.

8. (withdrawn): A composition according to claim 7, in which the nucleic acid molecules are associated with the same vesicle.

9. (withdrawn): A composition according to claim 1, in which the antigenic protein and the assistor protein are derived from a virus, preferably influenza.

10. (withdrawn): A composition according to claim 1 in which the nucleic acid is DNA, preferably plasmid DNA.

11. (withdrawn): A composition according to claim 1 which is a vaccine.

12. (withdrawn): A composition according to claim 11 adapted for subcutaneous, intramuscular, intravenous, intradermal, nasal, oral, mucosal or pulmonary administration.

13. (currently amended): A method of generating an immune response in a mammal by administering to the mammal a composition for the co-delivery to a cell of a nucleic acid and an assistor protein ~~comprising vesicles formed of amphiphilic components~~, wherein the nucleic acid operatively encodes an antigenic protein or portion thereof which shares at least one epitope with the assistor protein, the composition comprising said nucleic acid and said assistor protein

associated with liposomes formed from liposome forming materials, the liposomes having an average diameter in the range of 100-1000 μ m~~the same vesicles as one another~~, wherein

the antigenic protein and the assistor protein are ~~derived~~ from an infectious microorganism;

~~the vesicles are liposomes formed from liposome forming materials;~~

said nucleic acid and said assistor protein are both associated with the same liposomes;

the nucleic acid is entrapped in the intravesicular space of the liposomes; and

the nucleic acid and the assistor protein are present in a weight ratio in the range of 1000:1 to 1:1; and the immune response comprises an antibody response specific to the antigenic protein and/or assistor protein.

14. (canceled).

15. (previously presented): A method according to claim 13 in which the immune response involves stimulation of cytotoxic T-lymphocytes.

16. (previously presented): A method according to claim 13 which confers immunity against infection by an infectious virus.

17. (withdrawn): A process for forming a liposomal composition comprising the steps

(a) providing an aqueous suspension of small unilamellar (SUVs) formed of liposome forming materials;

(b) contacting the aqueous suspension of SUVs with nucleic acid which operatively encodes an antigenic protein to form an SUV-nucleic acid suspension;

(c) dehydrating the SUV-nucleic acid suspension to provide a dehydrated mixture; and
(d) rehydrating the dehydrated mixture in an aqueous resuspending medium to form a suspension of nucleic acid containing liposomes,
including the step of introducing an assistor protein whereby the nucleic acid containing liposomes are associated with said assistor protein.

18. (withdrawn): A process according to claim 17 in which the assistor protein is contacted with the aqueous suspension of SUV's before, during or after step b and before step c.

19. (withdrawn): A process according to claim 17 in which the assistor protein is present in the resuspending medium.

20. (withdrawn): A process according to claim 17 in which the liposome forming materials comprise at least one phospholipid and at least one sterol.

21. (withdrawn): A process according to claim 20 in which the materials comprise at least one cationic compound and the liposomes have an overall cationic charge.

22. (withdrawn): A process according to claim 17 wherein the weight ratio of nucleic acid to liposome forming materials is in the range 1:100 to 1:1000, preferably 1:100 to 1:300.

23. (withdrawn): A process according to claim 17 wherein the weight ratio of nucleic acid to assistor protein is in the range 1000:1 to 1:1, preferably 30:1 to 5:1.

24. (withdrawn): A process according to claim 17 wherein the dehydration is by freeze-drying.

Andrew David BACON, *et al.*
Appln. No. 10/520,169
Amendment Under 37 CFR 1.116

25. (previously presented): A method according to claim 14 wherein the antigenic protein is derived from Hepatitis virus.